Citizen Petition Concerning 5 CFR 5501.101(c)(2) – "10% rule"

Division of Dockets Management

Food and Drug Administration

Department of Health and Human Services

5630 Fishers Lane, rm. 1061

Rockville, MD 20852

Action Requested

The undersigned submits this petition under the Standards of Ethical Conduct for Employees of the Executive Branch contained in 5 CFR part 2635 under laws enforced by the Office of Government Ethics for which authority has been delegated to the Commissioner of Food and Drugs and the HHS regulations regarding conduct at 45 CFR part 73 to request the Commissioner of Food and Drugs to amend or revoke 5 CFR 5501.101(c)(2) based upon a review of the basis, intended purpose (e.g. protection of the public health and welfare) and actual societal needs as weighed against the economic and other impact on FDA employees, by an independent expert third party such as the Securities and Exchange Commission.

The section of regulation subject of this petition reads:

> 5 CFR 5501.101(c)(2) Significantly regulated organization means an organization for which the sales of products regulated by the Food and Drug Administration (FDA) constitute ***ten percent*** or more of annual gross sales in the organization's previous fiscal year; where an organization does not have a record of sales of FDA-regulated products, it will be deemed to be significantly regulated if its operations are solely in fields regulated by FDA. (emphasis added)

For the purposes of this petition, this regulation will be referenced as the "10 percent rule."

By definition, 5 CFR 5501 is a "Supplemental Regulation" to the Standards of Ethical Conduct for Employees of the Executive Branch contained in 5 CFR part 2635 promulgated by the Office of Government Ethics (OGE). As a supplemental regulation, 5 CFR 5501 should operate within the parameters established by the overarching OGE regulations. The OGE regulations are well crafted, intelligent and reasonable. They provide protection to the American public from inappropriate or unethical behaviors and actions on the part of Federal employees. At the same time, they do not impose unreasonable restrictions on the rights of Federal employees.

The OGE regulations set forth the following parameters in order to protect both the public's and government's interests while observing and protecting the rights of Federal employees:

5 CFR 2635.101(a)
Public service is a public trust. Each employee has a responsibility to the United States Government and its citizens to place loyalty to the constitution, laws and ethical principles above private gain.

2005P-0090

CP1

5 CRF 2635.101(b)(2)
Employees shall not hold financial interests that conflict with the ***conscientious performance of duty.***

5 CFR 2635.101(b)(14)
Employees shall endeavor to avoid any actions creating the appearance that they are violating the law or the ethical standards set forth in this part. Whether particular circumstances create an appearance that the law or these standards have been violated ***shall be determined from the perspective of a reasonable person*** with knowledge of the relevant facts.

5 CFR 2635.401
an employee is prohibited in accordance with Sec. 2635.402 of this subpart from participating in an official capacity in any particular matter in which, to his knowledge, he or any person whose interests are imputed to him has a financial interest, if the particular matter will have ***a direct and predictable effect on that interest.***

Direct and predictable effect is defined in 5 CFR 2635.402(b)(1):
A particular matter will have a direct effect on a financial interest if there is a ***close causal link between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest.*** An effect may be direct even though it does not occur immediately. A particular matter will not have a direct effect on a financial interest, however, if the chain of causation is attenuated or is contingent upon the occurrence of events that are ***speculative*** or that are independent of, and unrelated to, the matter.

5 CFR 2635.402(b)(4) requires personal and substantial participation in order for an interest or action to be prohibited. Personal and substantial is defined in this regulation:

To participate personally means to participate directly. It includes the direct and active supervision of the participation of a subordinate in the matter. To participate substantially means that the employee's involvement is of significance to the matter. Participation may be substantial even though it is not determinative of the outcome of a particular matter. ***However, it requires more than official responsibility, knowledge, perfunctory involvement, or involvement on an administrative or peripheral issue.*** A finding of substantiality should be based not only on the effort devoted to a matter, but also on the importance of the effort.

Note that 5 CFR 2635.402(c) provides for waivers when participation is deemed inconsequential to the matter or disqualification from participation in a particular matter as a remedy for obviating a conflict of interest.

Directed Divestiture is based on a determination that a SUBSTANTIAL conflict exists, not because of the possibility or appearance of a conflict of interest:

5 CFR 2635.402(e)(2)

An employee may be required to sell or otherwise divest himself of the disqualifying financial interest if his continued holding of that interest is prohibited by statute or by agency supplemental regulation issued in accordance with Sec. 2635.403(a), or if the agency determines in accordance with Sec. 2635.403(b) that ***a substantial conflict exists between the financial interest and the employee's duties or accomplishment of the agency's mission***.

Statement of Grounds

1 - This regulation needs to balance its adverse effect on employees against the need for protection of the public health and welfare and government interests from undue influence or actual conflicts of interest. It should conform to the parameters set forth in the overarching OGE regulations as explained above.

2 – In response to several inquiries, I have been advised that no one at FDA knows the origins of the "10 percent rule."

3 – Responsible authorities in FDA have been unable to provide the logic or rational for this definition of "substantially regulated." The Agency needs a sound basis for the determination that a financial holding is "substantially regulated." In the absence of a lawful, rational, reasonable basis, the regulation is arbitrary and capricious. FDA does not regulate industry in a manner that is arbitrary and capricious, it should not regulate its employees this way.

4 - Even if founded on some reasonable basis, this was done several decades ago and the nature of American business has changed. Corporate mergers, conglomerations and expansion into multiple product lines have dramatically altered the product lines of numerous businesses. For example, sometime during 1996, the Wal-Mart company expanded its foods related businesses increasing their gross sales from FDA regulated products to more than 10 percent. When that happened, virtually overnight, Wal-Mart became a prohibited financial holding causing unnecessary hardship for a large number of FDA employees with no attendant benefit to the American public.

5 – FDA states that it wants to attract the best candidates as employees. However, by necessitating divestiture of any financial holding deemed to be "significantly regulated" under the 10 percent rule, this rule exerts a strong "chilling effect" on recruitment efforts.

6 – Discussions of this rule with members of the public, FDA employees, FDA management and FDA ethics officials have revealed NO views or information that is unfavorable to either the review requested by this petition or to rescission or revision of 5 CFR 5501.101(c)(2).

Environmental Impact

No environmental impact is anticipated by revision or revocation of this regulation. I am requesting categorical exclusion from the requirement for an environmental impact assessment under 21 CFR 10.30(C)(A).

Economic Impact

Neither the actions requested by this petition nor rescission nor revision of 5 CFR 5501.101(c)(2) will have any economic impact on any industry regulated by the Food and Drug Administration (FDA).

Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) Arthur K. Yellin 2/25/2005

(Name of petitioner) Arthur K. Yellin

(Mailing address) 16904 Vine Court

Olney, MD 20832-2941

(Telephone number) 301-443-6597 x 146